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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1656

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,663

Applicant(s)

YANG ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-50 and 55-68 is/are pending in the application.
- 4a) Of the above claim(s) 57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50, 55, 56 and 59-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
2. Applicant's election with traverse of Group I (claims 48-50, 55-56 and 59-68) on July 20, 2005 is acknowledged.
3. The traversal is on the grounds that the claimed methods are all examined because there is no burden of search. Applicant states that although the objective/endpoint of each method differs the agent used is the same thus, the methods should not be restricted. This argument is not persuasive as the methods have different method steps and results which is a materially different process, thus patentably distinct. However, if applicant is willing to make a statement on the record that a reference that anticipates or renders obvious Group I would also anticipate or render obvious Group II then the search would be viewed as co-extensive and the Groups would be rejoined. The burden of search of the claimed invention is established by the status in the art as each invention has acquired a different status. MPEP chapter 800 state that a restriction requirement is proper if the inventions can be shown to be independent and/or distinct (related or unrelated). Although the methods are related by the use of the same agent, they are none- the-

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less different, thus subject to restriction practice based on the requirements set forth in chapter 800 of the MPEP. Therefore, the restriction requirement is deemed proper and is final.

Claim Disposition

4. Claims 1-47 and 51-54 have been cancelled. Claims 48-50, 55 and 57-67 have been amended. Claims 48-50 and 55-68 are pending. Claims 40-50, 55-56 and 59-68 are under examination. Claims 57-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 20, 2005.

Information Disclosure Statement

5. The information disclosure statement filed on January 26, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because items listed on the information disclosure statement are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. It is noted that applicant state that copies of the references were provided, however, none have been found. It is suggested that Applicant resubmit the references for consideration. A line has been drawn through all references listed on the PTO-1449 form that are non-patent literature, all others have been considered.

Drawing

6. The Drawings filed on January 26, 2004 have been accepted by the Examiner.

Specification

7. The specification is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TWEEN-20[®], TRIS[®], for example, have been noted in this application (see page 62). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction of the above is required.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 48-50, 55-56 and 59-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method of inactivating heparin or low molecular weight heparin with purified protamine. The claims are defined only by functional properties, not by a structure. Thus, there is no indication of which purified protamine the claimed invention is directed to. Note for example that claim 67 is directed to a second protamine which provides evidence that there can be more than one protamine, however, no structure is provided. In addition the claims are directed to a method that utilizes the undefined protamine and a second coagulant (see claim 63) which is also undefined. Furthermore, the art teaches that protamine given to neutralize heparin after extracorporeal circulation can trigger a catastrophic reaction in some patients (see Tan et al. *Anesthesiology*, Feb. 1989, vol. 70, no. 2, pages 267-75). Therefore, the claimed invention needs to adequately describe the protamine intended in the method. Thus the claims lack adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). Therefore, a biomolecule sequence described only by a functional characteristic,

without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *See MPEP 2163.*

Further, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993). *See MPEP 2163.*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 48-50, 55-56 and 59-68 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 55 and the dependent claims hereto are indefinite for the recitation of "at least a first purified protamine" because it is unclear if this phrase means there is a (a) second or subsequent protamine or (b) first purification of the product. It is suggested that the term "first" is deleted from the claim. Claim 55 and its dependents are also indefinite for the recitation of "reduced immunoresponsiveness or toxicity" as it is unclear how much of a reduction, what quantity? In addition, the phrase "between about" is indefinite as this represents two different ranges, for example 'between' is a specific range and 'about' represents a range outside of the between range. Deletion of one of these terms is suggested. Claim 55 and the dependent claims hereto is also indefinite for the recitation of "molecular weight of between about 400 and about 2500" without a standard, thus it is unclear what method was used to obtain this molecular weight. Is it via SDS-PAGE for example. It is suggested that the standard/instrumentation used is inserted into the claim.

Claims 59-62 and 64 lacks clear antecedent basis as the independent claim 55 is directed to a method to inactivate heparin by administering a purified protamine in a composition, thus, the health conditions of the mammal is not a step in the method of inactivation of heparin. The necessary step required is contacting the heparin with the protamine composition as recited in claim 55.

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Art of Record

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hubbell et al. (U.S. 6,468,731) heparin binding domains via construction of fusion proteins to enhance healing. Hubbell is silent on inactivating heparin with a protamine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

HOPE ROBINSON
PATENT EXAMINER

10/1/05